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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,464	11/30/2001	William C. Tacon	12905	9284

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,464	TACON ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *11-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 18-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/13/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A response of 3/16/05 to a restriction requirement of 6/16/04 elected with traverse invention I claims 1-10, and amended claims 11-13, 15, 18 and 24.

The traverse is on the ground that due to amendments, all claims are now dependent directly or indirectly from claim 1.

The traverse based on amending the claims to depend from claim 1 is persuasive only with respect to combining claims 18-29 of invention VI with claims 1-10 of invention I, and combining claims 13 and 14 of invention IV with claim 11 of invention II. Claims 11-17 of inventions II-V being dependent on claim 1 does not obviate the restriction of inventions I and VI from the methods of inventions II, III and V since the microparticle and composition of inventions I and VI can be prepared by a method different than required by the methods of inventions II, III and V. The methods of inventions II, III and V are different methods requiring different steps such that the method of each invention can be performed without performing the method of any other invention. This is not changed by making the claims of inventions II, III and V dependent on claim 1 of invention I.

In regard to classification, applicants assert that claims 11 is not in 424/497 since the claim does not require a coated or impregnated particle. However, claim 11 is making a microparticle for delivery of a therapeutic material, and the claim does not exclude the therapeutic material being in the microparticle. A microparticle is a shape within the scope of 424/489 which 424/497 requires. Applicants

assert that claim 12 does not require a special physical form as required by 424/400. However, the claim is making a microparticle, and a microparticle is a special physical form. This also applies to claims 13 and 14 that now depend on claim 12. Applicants urge that there is nothing in claims 15-17 to suggest a pepide as required by 514/2. However, claims 15-17 require a protein for pulmonary function, and a protein is a peptide within the scope of 514/2.

Claims 11-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/16/05.

Claims 1-10 and 18-29 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 18-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Bridging lines 2 and 3 of claim 1, it is uncertain how "prefabricated in a particular geometric shape" defines the microparticle. Shapes that this limitation encompasses and excludes

is uncertain. Any microparticle will have a prefabricated particular geometric shape since the microparticle inherently has a shape, and the shape is fabricated in a process of making the microparticle. A spherical microparticle has a spherical shape, and the spherical shape is produced during manufacture of the microparticle.

Claim 2 encompasses a diameter or width being the same as a width. When the same, it is uncertain how one would know which dimension is the diameter or width and which is the width. Furthermore, if the microparticle is a sphere, it would have only a diameter and not a width and thickness.

Claim 18 is unclear as to the meaning of "shaped, particulate dry powder composition". It is uncertain how a powder can be shaped. Additionally, claim 18 is unclear as to the relationship of the physiologically acceptable polymer to the microparticle of claim 1 required by claim 18. Claim 1 requires the microparticle to comprise a polymer matrix. Is the physiologically acceptable polymer of claim 18 in addition to the polymer matrix of the microparticle of claim 1, or does the physiologically acceptable polymer have some other relationship to the polymer matrix?

Dependent claim 19 is confusing by not having clear antecedent basis for "said shaped particles". Claim 18 does not require shaped particles.

Dependent claim 20 is unclear by not having clear antecedent basis for "the diameter" by not requiring a shape having a diameter.

Furthermore, claim 20 depends on claim 19 that requires a cube, rectangle or snowflake that do not have a diameter.

In claim 24, the abbreviation "PLGA" should be in parenthesis and preceded by the full name as when using the abbreviations PCPH AND PGA.

In line 2 of claim 27, "from the group consisting essentially of" is unclear as to members of the group since "essentially" permits members other than recited.

Dependent claim 28 is unclear by not having clear antecedent basis for "the shaped particle" and "the active therapeutic agent". The claim is further uncertain as to the meaning of "second polymer" since it is not clear as to the polymer that is the first polymer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of

each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 18-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,985,309) or (5,874,064) or Hanes et al (5,855,913) in view of Ferrari et al (6,355,270 B1) and Ferrari (6,107,102).

The claims are drawn to a microparticle for use in pulmonary delivery of a therapeutic material. The microparticle comprises a polymer matrix prefabricated in a particular geometric shape. Also claimed is a shaped, particulate dry powder composition comprising the microparticle and a biologically active agent.

Edwards et al ('309 and '064) disclose microparticles for pulmonary delivery or inhalation of a therapeutic agent. The microparticles can have a diameter of 5-30 microns, and be formed of a copolymer or blend of polymers, and the polymers can be selected to provide a desired rate of degradation. Polymers that can be used include PGA, PLGA, or other polymers such as polymers of acrylic or methacrylic acid. An excipient such as a surfactant may be present. Therapeutic agents that can be delivered include hormones, proteins, antibiotics and G-CSF. For example, see the '309 patent, paragraph bridging cols 3 and 4; col 6, line 1 to col 7, line 67; col 10, line 48; col 11, line 52; col 11, line 61 to col 12, line 47; and col 13, lines 10-15. The '064 and '913 patents have similar disclosures.

Ferrari and Ferrari et al disclose (abstracts of patents) microfabricated microdevices or microparticles having a non-spherical shape for delivery of therapeutic agents. The shape, size and composition of the microdevices or microparticles depend on the selected application. The shape may be a disk having a diameter of about 50 nm to about 3 microns and a thickness of about 10 nm to about 1 micron ('102 patent, col 5, lines 25-30). Alternatively, the disk can have a diameter of about 100-5000 microns and a thickness of about 10-100 microns ('270 patent, col 4, lines 47-50). The microdevices or microparticles can be formed from a polymer such as polyglycolic acid ('102 patent, col 8, line 35, and '270 patent, col 6, line 13). When using a spherical shape, physical-contact area between particles and target-site cells such as particle binding to a cell is more limiting than when using a particle having more planar surfaces ('102 patent, col 2, lines 8-13).

It would have been obvious to provide the microparticles used by Edwards et al ('309 or '064) or Hanes et al for therapeutic agent delivery with a non-spherical disk shape as disclosed by Ferrari and Ferrari et al when using non-spherical disk shaped microparticles for therapeutic agent delivery to obtain greater physical-contact area between the particles and target-site cells as disclosed by Ferrari (col 2, lines 8-13). The conditions of the dependent claims are disclosed by the references, or would have been obvious from conditions disclosed by the references. A powder composition as required by claims 18-29 would have been obvious for pulmonary

delivery or inhalation as disclosed by Edwards et al. For example, see the '064 patent at col 10, line 48 to col 11, line 15. Having an additional polymer present as in claims 9 and 28 would have been obvious to provide a preferred degradation rate of the microparticles and/or release rate of the therapeutic agent as suggested by Edwards et al ('309) or '064) or Hanes et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 751-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
7/22/05